IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 20-_____
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendant.	)	
	)	
	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Vanda Pharmaceuticals Inc. ("Vanda") for its Complaint against Defendant Teva Pharmaceuticals USA, Inc. ("Teva") alleges as follows:

I. THE PARTIES

1. Plaintiff Vanda is a Delaware corporation with its principal place of business at 2200 Pennsylvania Ave. NW, Suite 300E, Washington, DC 20037. Vanda is a pharmaceutical company that focuses on the development and commercialization of new medicines to address unmet medical needs, including Hetlioz® (tasimelteon oral capsules), for the treatment of Non-24-Hour Sleep-Wake Disorder ("Non-24").

2. On information and belief, Defendant Teva is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054.

II. NATURE OF THE ACTION

3. This is an action arising under the patent laws of the United States (Title 35, U.S. Code, §§ 100, *et seq.*) based upon Teva's infringement of one or more claims of Vanda's U.S. Patent Nos. 10,610,510 ("the '510 patent") and 10,610,511 ("the '511 patent"), which, in relevant

part, generally relate to the use of tasimelteon in the treatment of circadian rhythm disorders or sleep disorders.

4. Vanda is the holder of approved New Drug Application No. 205,677 for Hetlioz® (tasimelteon) capsules, 20 mg, which was approved by the Food and Drug Administration ("FDA") on January 31, 2014, for the treatment of Non-24, a circadian rhythm sleep disorder.

5. Tasimelteon is the active ingredient in Hetlioz®.

6. On information and belief, Teva filed Abbreviated New Drug Application No. 211601 (the "ANDA") under § 505(j) of the Federal Food, Drug, and Cosmetic Act (the "FFDCA"), to obtain approval to commercially manufacture and sell generic tasimelteon capsules in its 20 mg strength for the treatment of Non-24 ("Teva's ANDA Product").

7. On information and belief, Teva made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that, in its opinion and to the best of its knowledge, the '510 and '511 patents are invalid, unenforceable, and/or that certain claims will not be infringed by Teva's ANDA Product.

8. Vanda received written notice of Teva's ANDA and Paragraph IV Certification as to the '510 and '511 patents on July 10, 2020 ("Notice Letter"), along with an enclosed statement of Teva's alleged factual and legal bases for stating that the '510 and '511 patents are invalid, unenforceable, and/or will not be infringed by Teva's ANDA Product ("Detailed Statement").

9. Teva's Detailed Statement does not provide any factual bases or other statements alleging that the '510 and '511 patents are unenforceable.

10. Teva's Detailed Statement does not provide any separate factual bases for stating that the '511 patent will not be infringed by Teva's ANDA Product apart from arguing that the '511 patent is invalid.

11. This action is being commenced within 45 days of receipt of Teva's Notice Letter.

12. Teva has infringed one or more claims of each of the '510 and '511 patents under 35 U.S.C. § 271(e)(2)(A) by virtue of the filing of the Teva ANDA with a Paragraph IV Certification and seeking FDA approval of the Teva ANDA prior to the expiration of the '510 and '511 patents or any extensions thereof.

13. Teva has infringed one or more claims of each of the '510 and '511 patents under 35 U.S.C. § 271(e)(2)(A) by virtue of the filing of the Teva ANDA seeking FDA approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States generic tasimelteon for the treatment of Non-24 prior to the expiration of the '510 and '511 patents or any extensions thereof.

III. JURISDICTION

14. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has subject matter jurisdiction over Vanda's patent infringement claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

15. This Court has personal jurisdiction over Teva because Teva is incorporated in the State of Delaware.

16. On information and belief, Teva's registered agent for service of process is Corporate Creations Network Inc., with an address at 3411 Silverside Road #104, Tatnall Building, Wilmington, Delaware 19810.

17. On information and belief, Teva is in the business of manufacturing generic pharmaceuticals that it distributes or has distributed in the State of Delaware and throughout the United States.

18. Teva has committed, or aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement that will lead to foreseeable harm and injury to Vanda, which manufactures Hetlioz® for sale and use throughout the United States, including in this Judicial District. On information and belief, and as indicated by the Notice Letter, Teva prepared and filed ANDA No. 211601 with the intention of seeking to market generic tasimelteon nationwide, including within this Judicial District.

19. On information and belief, Teva plans to market and sell generic tasimelteon in the State of Delaware, list generic tasimelteon on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursement for sales of the Teva ANDA Product in the State of Delaware, either directly or through one or more of Teva's wholly owned subsidiaries, agents, and/or alter egos.

20. On information and belief, Teva knows and intends that its proposed generic tasimelteon product will be distributed and sold in Delaware and will thereby displace sales of Hetlioz®, causing injury to Vanda. Teva intends to take advantage of its established channels of distribution in Delaware for the sale of the Teva ANDA Product.

IV. VENUE

21. Venue is proper in this Judicial District under 28 U.S.C. § 1400(b) because Teva is incorporated in the State of Delaware.

V. THE PATENTS-IN-SUIT

(U.S. PATENT NOS. 10,610,510 and 10,610,511)

U.S. Patent No. 10,610,510

22. The allegations above are incorporated herein by reference.

23. The ’510 patent covers, generally, a method of treating circadian rhythm disorders by administration of tasimelteon to patients who may be smokers.

24. As explained in the ’510 patent, smoking “has been found to increase the clearance of tasimelteon, thereby reducing patient exposure” to the drug, and therefore, administration of tasimelteon to patient who is a smoker may require, in some cases, “reducing or eliminating the individual’s smoking.” The ’510 patent further explains that aspects of the invention, as they relate to the effects of smoking on tasimelteon exposure include, without limitation: “treating a patient with tasimelteon wherein the patient is a smoker” with a method comprising “instructing the patient to reduce or eliminate smoking.”

25. Vanda is the owner of all rights, title, and interest in the ’510 patent, entitled “Treatment Of Circadian Rhythm Disorders.” The USPTO duly and legally issued the ’510 patent on April 7, 2020, to Marlene Michelle Dressman, John Joseph Feeney, Louis William Licamele, and Mihael H. Polymeropoulos as inventors, which was assigned to Vanda. A true and correct copy of the ’510 patent is attached to this Complaint as Exhibit A.

26. The ’510 patent generally claims methods of treating circadian rhythm disorders using tasimelteon based on whether the patient is a smoker.

U.S. Patent No. 10,610,511

27. The allegations above are incorporated herein by reference.

28. The '511 patent covers, generally, the administration of an effective dose of tasimelteon without food or under fasted conditions to treat patients suffering from a circadian rhythm disorder or sleep disorder.

29. As explained in the '511 patent, one embodiment of the invention "provides a method for administering tasimelteon to a human patient that comprises orally administering an effective dose of tasimelteon under fasted conditions." The '511 patent further explains, "[t]asimelteon may be administered where, for example, the patient is being treated for a circadian rhythm disorder or for a sleep disorder, including, for example, Non-24 Disorder."

30. Vanda is the owner of all rights, title, and interest in the '511 patent, entitled "Method of Treatment." The USPTO duly and legally issued the '511 patent on April 7, 2020, to Marlene Michelle Dressman, Mihael H. Polymeropoulos, and Paolo Baroldi as inventors, which was assigned to Vanda. A true and correct copy of the '511 patent is attached to this Complaint as Exhibit B.

31. The '511 patent generally claims methods of treating circadian rhythm disorders or sleep disorders using tasimelteon based on instructing the patient to take tasimelteon without food or under fasted conditions.

VI. COUNT I

(INFRINGEMENT OF THE '510 PATENT)

32. The allegations above are incorporated herein by reference.

33. Teva filed the Teva ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell generic tasimelteon for the treatment of Non-24 before the expiration of the '510 patent and any extensions thereof.

34. Teva's Notice Letter states that Teva filed the ANDA seeking approval to manufacture, use, offer to sell, and sell generic tasimelteon in its 20 mg strength for the treatment of Non-24 before the expiration of the '510 patent. The Notice Letter represents that an Amendment to Teva's ANDA was submitted with a Paragraph IV Certification that the '510 patent purportedly is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Teva's ANDA Product.

35. Teva thus has actual knowledge of the '510 patent.

36. The FDA-approved Hetlioz® Label instructs prescribers that "HETLIOZ is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24)."

37. The Hetlioz® Label further instructs prescribers that "[t]he recommended dosage of HETLIOZ is 20 mg per day taken before bedtime, at the same time every night."

38. The Hetlioz® Label also teaches prescribers that "[s]moking causes induction of CYP1A2 levels. The exposure of tasimelteon in smokers was lower than in non-smokers and therefore the efficacy of HETLIOZ may be reduced in smokers [*see Clinical pharmacology (12.3)*]." The Hetlioz® Label further teaches prescribers: "[t]asimelteon exposure decreased by approximately 40% in smokers, compared to nonsmokers [*see Use in Specific Populations (8.7)*]."

39. On information and belief, the Teva ANDA seeks approval for a 20 mg tasimelteon oral capsule for the treatment of Non-24.

40. Thus, the use of Hetlioz® and any generic tasimelteon for the treatment of Non-24 is covered by the '510 patent and Vanda has the right to enforce the '510 patent and sue for infringement thereof.

41. The ’510 patent is listed in FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange Book”) for Hetlioz® in its 20 mg strength.

42. On information and belief, the Teva ANDA essentially copies the Hetlioz® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs, recommends, encourages, teaches, and/or suggests that prescribers infringe claims 1–13 of the ’510 patent.

43. On information and belief, if Teva’s ANDA is approved, prescribers and patients will follow the instructions in the proposed label for Teva’s ANDA Product and administer Teva’s ANDA Product in a manner that would infringe claims 1–13 of the ’510 patent.

44. On information and belief, Teva’s ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe claims 1–13 of the ’510 patent.

45. Teva has infringed the ’510 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Teva ANDA to FDA seeking to obtain approval for generic tasimelteon in its 20 mg strength for the treatment of Non-24, which is covered by one or more claims of the ’510 patent, prior to the expiration of the ’510 patent.

46. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under the Teva ANDA would infringe directly or contribute to or induce the infringement of one or more claims of the ’510 patent, including claims 1–13 under 35 U.S.C. § 271(a), (b), and/or (c).

47. Vanda seeks entry of an order requiring that Teva amend its Paragraph IV Certification in the Teva ANDA to a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) (“Paragraph III Certification”) as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

48. Vanda seeks entry of an order declaring that Teva has infringed the ’510 patent by virtue of submitting its ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

49. Vanda seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Teva ANDA be a date that is not earlier than the expiration of the '510 patent or any later expiration of exclusivity for the '510 patent to which Vanda becomes entitled.

50. Vanda will be irreparably harmed if Teva is not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the '510 patent. Pursuant to 35 U.S.C. § 283, Vanda is entitled to a permanent injunction against further infringement. Vanda does not have an adequate remedy at law.

51. On information and belief, Teva's statement of the factual and legal bases for its opinion regarding the invalidity and noninfringement of the '510 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional and Vanda is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

52. To the extent Teva commercializes its product, Vanda will also be entitled to damages under 35 U.S.C. § 284.

VII. COUNT II

(INFRINGEMENT OF THE '511 PATENT)

53. The allegations above are incorporated herein by reference.

54. Teva filed the Teva ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell generic tasimelteon to be taken under fasted conditions or without food for the treatment of Non-24 before the expiration of the '511 patent and any extensions thereof.

55. Teva's Notice Letter states that Teva filed the ANDA seeking approval to manufacture, use, offer to sell, and sell generic tasimelteon in its 20 mg strength for the treatment of Non-24 before the expiration of the '511 patent. The Notice Letter represents that an

Amendment to Teva's ANDA was submitted with a Paragraph IV Certification that the '511 patent purportedly is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Teva's ANDA Product.

56. Teva thus has actual knowledge of the '511 patent.

57. The FDA-approved Hetlioz® Label instructs prescribers that "HETLIOZ is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24)."

58. The Hetlioz® Label further instructs prescribers that "[t]he recommended dosage of HETLIOZ is 20 mg per day taken before bedtime, at the same time every night."

59. The Hetlioz® Label also instructs prescribers that "HETLIOZ should be taken without food *[see Clinical Pharmacology (12.3)]*."

60. On information and belief, the Teva ANDA seeks approval for a 20 mg tasimelteon oral capsule to be taken under fasted conditions or without food for the treatment of Non-24.

61. Thus, the use of Hetlioz® and any generic tasimelteon for the treatment of Non-24 is covered by the '511 patent and Vanda has the right to enforce the '511 patent and sue for infringement thereof.

62. The '511 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for Hetlioz® in its 20 mg strength.

63. On information and belief, the Teva ANDA essentially copies the Hetlioz® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs, recommends, encourages, teaches, and/or suggests that prescribers infringe claims 1–2 and 4–19 of the '511 patent.

64. On information and belief, if Teva's ANDA is approved, prescribers and patients will follow the instructions in the proposed label for Teva's ANDA Product and administer Teva's ANDA Product in a manner that would infringe claims 1–2 and 4–19 of the '511 patent.

65. On information and belief, Teva's ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe claims 1–2 and 4–19 of the '511 patent.

66. Teva has infringed the '511 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Teva ANDA to FDA seeking to obtain approval for generic tasimelteon in its 20 mg strength to be taken without food or under fasted conditions for the treatment of Non-24, which is covered by one or more claims of the '511 patent, prior to the expiration of the '511 patent.

67. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under the Teva ANDA would infringe directly or contribute to or induce the infringement of one or more claims of the '511 patent, including claims 1–2 and 4–19 under 35 U.S.C. § 271(a), (b), and/or (c).

68. Vanda seeks entry of an order requiring that Teva amend its Paragraph IV Certification in the Teva ANDA to a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("Paragraph III Certification") as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

69. Vanda seeks entry of an order declaring that Teva has infringed the '511 patent by virtue of submitting its ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

70. Vanda seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Teva ANDA be a date that is not earlier than the expiration of the '511 patent or any later expiration of exclusivity for the '511 patent to which Vanda becomes entitled.

71. Vanda will be irreparably harmed if Teva is not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the '511 patent. Pursuant to 35 U.S.C. § 283, Vanda is entitled to a permanent injunction against further infringement. Vanda does not have an adequate remedy at law.

72. On information and belief, Teva's statement of the factual and legal bases for its opinion regarding the invalidity and noninfringement of the '511 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional and Vanda is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

73. To the extent Teva commercializes its product, Vanda will also be entitled to damages under 35 U.S.C. § 284.

PRAYER FOR RELIEF

WHEREFORE, Vanda respectfully requests that this Court enter judgment in its favor against Teva and grant the following relief:

A. an adjudication that Teva has infringed directly, contributed to, or induced the infringement of one or more claims of the '510 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to FDA the Teva ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic tasimelteon for the treatment of Non-24 before the expiration of the '510 patent;

B. an adjudication that Teva has infringed directly, contributed to, or induced the infringement of one or more claims of the '511 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to FDA the Teva ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic tasimelteon for the treatment of Non-24 before the expiration of the '511 patent;

C. a declaration that Teva will infringe directly, contribute to, or induce the infringement of one or more claims of the ’510 patent under 35 U.S.C. § 271(a), (b), and/or (c) if it markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States generic tasimelteon for the treatment of Non-24 before the expiration of the ’510 patent;

D. a declaration that Teva will infringe directly, contribute to, or induce the infringement of one or more claims of the ’511 patent under 35 U.S.C. § 271(a), (b), and/or (c) if it markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States generic tasimelteon for the treatment of Non-24 before the expiration of the ’511 patent;

E. an order requiring that Teva amend its Paragraph IV Certification to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A);

F. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Teva ANDA for generic tasimelteon be a date that is not earlier than the date of the expiration of the ’510 patent or any later period of exclusivity to which Vanda is or may become entitled;

G. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Teva ANDA for generic tasimelteon be a date that is not earlier than the date of the expiration of the ’511 patent or any later period of exclusivity to which Vanda is or may become entitled;

H. a permanent injunction enjoining Teva, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the ’510 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Teva ANDA;

I. a permanent injunction enjoining Teva, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the ’511 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Teva ANDA;

J. an order enjoining Teva, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the ’510 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Teva ANDA;

K. an order enjoining Teva, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the ’511 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Teva ANDA;

L. an assessment of pre-judgment and post-judgment interest and costs against Teva, together with an award of such interest and costs, in accordance with 35 U.S.C. § 284;

M. an award to Vanda of its attorneys’ fees incurred in connection with this lawsuit pursuant to 35 U.S.C. § 285; and

N. such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Derek J. Fahnestock

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